Transonic Systems Inc.
The Flow Measurement Specialists

SEP 7 2012

510(k) SUMMARY
Summary of Safety & Effectiveness

Submitter's Name & Address: Transonic Systems Inc
34 Dutch Mill Road,
Ithaca, NY 14850

Contact Person & Telephone: Naveen Thuramalla
607-257-5300 (*326)

Date Summary Prepared: Dec 12, 2011

Device Name:
Classification Name: Computer, Diagnostic, Pre-programmed, Single-function, 21 CFR 870.1435.
Product Class and Code: DXG and Class II
Classification Panel: Cardiovascular
Common/Usual Name: Cardiac output, Hemodynamic monitor
Proprietary Name: COstatus System for Infants

Predicate Devices:
K080116: Transonic COstatus cardiac output system (for use with 2 years and older patients)

K980906: Transonic hemodialysis monitor, Cardiac

K023960: LIDCOPLUS hemodynamic monitor system

Device Description:

In accordance with section 510(k) for the Federal Food, Drug, and Cosmetic Act, Transonic Systems Inc. intends to introduce into interstate commerce the Transonic COstatus system for use with infants and older, which is an apparatus based on indicator dilution techniques for the measurement of cardiac output; blood volumes and other associated hemodynamic parameters. The proposed device is a variation of the COstatus system (K080116) which can measure the same parameters in patients 2 years and above. The COstatus system uses a peristaltic pump to circulate a small volumes blood passed the sensors rather than using a hemodialysis circuit. The system can thereby be used on any patient with arterial and venous access lines. These

patients could be in the intensive care units (ICU), operating room (OR) or other such environments.

Components:

The components of the Transonic COstatus system are made of materials, which have been tested in accordance with the ISO Standard 10993 appropriate to their patient contact and therefore suitable for the intended use of this product.

COstatus system consists of the following components:

Model/Part #	Description
HCM101	Cardiac output monitor/meter
HC2T	Sensors
ADT2005D	Arteriovenous (AV) Loop – Tubing Set
ADT2005E	Arteriovenous (AV) Loop – Tubing Set
ADT2006E	Arteriovenous (AV) Loop – Tubing Set
ADT1020	Extension Set/ Sensor Adapter Tubing
HCS3011	AV Loop kit with ADT2005D AV Loop
HCS3021	AV Loop kit with ADT2005E AV Loop
HCS3022	AV Loop kit with ADT2006E AV Loop
HCS3002	Sensor Adapter Tubing Pack with ADT1020
HCP01	AV Loop Pump
HCR01	Printer
HFW1000	Fluid Bag Warmer
HCMD01	Data Transfer Module

Substantial Equivalence:

The Transonic COstatus System for use with Infants is similar in materials, form and intended use to the Transonic COstatus Cardiac Output system (K080116) and to Transonic Hemodialysis Monitor, Cardiac (K980906) which are used in the diagnostic assessment of cardiovascular status including cardiac output and associated hemodynamic parameters. Both these devices are marketed by Transonic Systems Inc. The device is also equivalent to the LIDCOplus hemodynamic monitoring system cleared by K023960 and marketed by LiDCO, Ltd.

The difference between COstatus system cleared by K080116 and the proposed device is that the new system would allow use of the system with infants (1 month of age and above) while the previous system was cleared for use with patients 2 years and above.

The difference between COstatus system and the HDO1 is that the COstatus system uses a peristaltic pump to draw a small volume of blood passed the sensors rather than using a Hemodialysis circuit. The system can thereby be used on any patient with arterial and venous access lines. The system can be used on patients in other clinical

settings such as an ICU, OR, etc. The LiDCOplus Hemodynamic Monitor also uses a small peristaltic pump, but uses lithium chloride as an indicator whereas the COstatus uses normal saline. The LiDCOplus Hemodynamic Monitor does not return withdrawn blood to the patient, but the COstatus runs as a closed loop returning all drawn blood. These differences do not raise any new issues of safety or effectiveness regarding the use of Transonic COstatus System with infants and above.

Safety and Effectiveness:

The COstatus monitoring system is deemed to be safe and effective based on the safety testing conducted in accordance with the IEC 60601-1 standard and the electromagnetic compatibility test report.

In addition to the bench testing, animal and clinical validation studies were also performed to establish equivalence of cardiac output measured by COstatus with those made by standard clinical methods such as thermodilution, etc.

Prior to shipment, the finished products are tested and must meet all required release specifications before distribution. The array of testing required for release include, but are not limited to; physical testing, visual examination (in process and finished product). The physical testing is defined by Quality Control Test Procedure documents. These tests are established testing procedures that ensure the products performance parameters conform to the product design specifications. The testing instruction records for each of the individually required procedures are approved, released, distributed and revised in accordance with document control cGMP"s.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 7 2012

Transonic Systems, Inc.
Mr. Naveen Thuramalla
34 Dutch Mill Road
Ithaca, NY 14850

Re: K113821
Trade/Device Name: Transonic COstatus Cardiac Output System
Regulation Number: 21 CFR 870.1435
Regulation Name: Single Function Pre-programmed Diagnostic Computer
Regulatory Class: Class II
Product Code: DXG
Dated: August 16, 2012
Received: August 17, 2012

Dear Mr. Thurmalla:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113821
pg. 1 of 1

Indications for Use Statement

510(k) Number (if known):

Device Name: Transonic Systems COstatus System for use with Infants

Indications for Use:

The Transonic COstatus system is indicated for use in patients 1 month or older with arterial and venous lines in the diagnostic assessment of cardiovascular status including cardiac output and associated hemodynamic parameters.

Prescription Use __X__ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113821